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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,546	02/16/2001	Sonya Franklin	875.037US1	5198

21186 7590 09/26/2003

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 09/26/2003

(9)

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,546

Applicant(s)

FRANKLIN, SONYA

Examiner

Charles L. Patterson, Jr.

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-- *Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --*

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 3, 19-26 and 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-18, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 3, 19-26 and 30-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

The disclosure is objected to because of the following informalities:

On page 8, lines 20-23, colors are mentioned. The figures filed 10/15/01 do not have colors. Applicant corrected the mention of colors on line 27-28 but did not correct them here.

On page 45, line 19, "Figure 2B" is mentioned. There is no such figure.

Appropriate correction is required.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite in the recitation of "engrailed". Applicant has shown the word used in a publication (Kissinger, et al. (AR)), but has not given a definition for the term or shown exactly where the term is defined. The reference refers to "engrailed homeodomain" and claim 9 refers to transcription factors. The term is apparently an adjective but the definition is unknown. The term is also used in numerous places in the specification and these recitations are not understood.

The previous 35 USC § 101 rejection is dropped in view of applicants pointing out where the specification states on page 3 that the synthetic peptide or polypeptide is a nuclease.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-18 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

On page 50, line 27 it is stated that "P3 comprises...(T₂₇-L₃₄ and E₄₂-K₅₇)". This is 34 residues while P3 (SEQ ID NO:2) is only 33 residues long. This is not understood. Also, it is not clear to what sequence these residues numbers refer. Applicant replies that "X_(n) denotes a numbering scheme", quoting page 50, line 29. The examiner understands that this is a numbering system but does not know the identity of the sequence that has these amino acids at positions 27, 34, 42 and 57. Applicant replies that these residues are "in the engrailed homeodomain" but the sequence and identity of this "engrailed homeodomain" is apparently not disclosed in the specification and it is not understood to what this is meant to refer.

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In addition, it is not understood how residues at one position, e.g. A at positions 43, can be substituted for R at position (19) as in the recitation of "A₄₃ → R₍₁₉₎", and "Q₄₄ → E₍₂₀₎". Applicant replies that this "indicates an alanine to arginine substitution at position 19 in a synthetic peptide of the invention which corresponds to the alanine residue at position 43 in the engrailed homeodomain (see Figure 2)...[and] a glutamine to glutamic acid substitution at position 44 in the engrailed homeodomain". This is also not understood. How can this refer to an alanine at position 19 when the recitation is "A₄₃"? This goes against the normal and accepted notations of amino acids at particular positions. Also, applicant's recitation of "a glutamine to glutamic acid substitution at position 44 in the engrailed homeodomain" is not consistent with the previous recitation. To be consistent, the recitation would have to be "a glutamine to glutamic acid substitution at position 20 in a synthetic peptide of the invention which corresponds to the glutamine residue at position 44 in the engrailed homeodomain", but again, this is not understood. Apparently there are some protein sequences that are not included in the instant specification such as the "engrailed homeodomain", and the disclosure of these sequence is deemed "essential matter" to the understanding of the instant invention.

On page 51, lines 5-7, it is stated that "sites of Ca(II) or Ln(III) binding are indicated by an x, sites of phosphate backbone contact with an o, and DNA base contacts with a * for representative P3". It is presumed that this refers to Figure 2 and an "o" and "*" are not seen in this figure.

On page 56, lines 12-14, it is stated that 25 μM EuP3 in the presence of 225 μM excess metal (lane 3) has a similar effect to 25 μM EuP3 alone", referring to Figure 8. However, on page 10 it is disclosed that lane 3 of Figure

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8 is DNA with 30 μ M "EuCl₃". Therefore the indicated recitation on page 56 is apparently false.

Claim 1 is drawn to a synthetic peptide with a DNA binding domain and a metal binding domain, with these two domains being the same. Apparently nowhere in the specification is it taught that these two domains are the same. What is apparently taught is that the peptides disclosed in the specification both bind a metal and possibly cleave a nucleic acid. It is not shown that the peptide "specifically binds a nucleic acid". Indeed, there is not shown to be anything "specific" for the nucleic acid cleavage, absent convincing proof to the contrary. Applicant replies that "the specification discloses that the DNA binding domain and the metal binding domain are substantially superimposable in the helix orientation, and so such a metal binding domain can be introduced to a DNA binding domain, e.g., by replacing the turn or loop in the DNA binding domain with the metal binding domain (page 3, lines 19-23)" and that "engrailed binds to a consensus sequence TCAATTAAAT (the underlining denotes the most conserved positions, see Desplan et al., Cell, 54, 1081 (1988), a copy is enclosed herewith), and pUC19 has two CAATTAA sequences". The recitation on page 3 does not mention turns or loops and it is not seen how the specification teaches that a metal binding domain has been introduced into a DNA binding domain. The significance of the CAATTAA sequence is not readily apparent and the indicated reference was not sent.

For the reasons discussed *supra*, it is maintained that one of ordinary skill in the art would not know how to make and/or use the invention from reading the instant specification. It is also maintained that this ordinary artisan would have had no assurance that the applicant had possession of the invention at the time of filing of the application. Also, as previously indicated, it appears that if the specification is shown to be enabled for any-


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thing, it should only be enabled for Eu/P3, Eu/P4a and Eu/EuP5L and the claims should be limited in scope to these embodiments.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
September 22, 2003